K071896

510(k) SUMMARY – Fox 940 Laser

FEB 22

Applicant Name:	Valam, Inc. 41 West 57th St. 6th Floor, New York, NY 10019
Contact Person:	Yosef Krespi, M.D.
Date Prepared:	February 4, 2008
Device Trade Name:	Fox 940 Laser
Device Common Name:	Diode Laser
Classification Name:	Laser Surgical Instrument
Predicate Devices:	Fox 810 (K062619), LaserPro (K040924)
Device Description:	Fox 940 is a diode laser with 940 nM wavelength and maximum 5 watt power output.
Intended Use:	Surgical applications requiring the ablation, vaporization, excision, incision, hemostasis, or coagulation of soft tissues in medical specialties including dermatology, gastroenterology, general surgery, genitourinary, gynecology, neurosurgery, otolaryngology, orthopedics, ophthalmology, pulmonology, and thoracic surgery.
Device Technological Characteristics and Comparison to Predicate Device(s):	The Fox 940 uses diodes to generate energy in the 940 nm range. Fibers deliver energy to the tissue. The Fox 810 Laser is the same system, but generates energy in the 810 nm range. The LaserPro is also a diode laser producing energy in the 940 nm range.
Performance Standards:	The Fox 940 Laser complies with the performance requirements of 21CFR 1040.10 and 1040.11, with permissible deviations defined in Laser Notice 50, dated July 26, 2001. The diode laser also complies with IEC 60601-1:1998 including amendment 1, IEC 60601-2-22:1995, and IEC 60825-1:1993 including amendments 1 and 2.
Conclusion:	The Fox 940 Laser is substantially equivalent to the predicate devices. It has similar intended uses and complies with the same safety and performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 22 2008

Valam, Inc.
% PPD Medical Device
Ms. Kirsten Paulson
Manager, Regulatory Affairs
3202 Tower Oaks Blvd, Suite 300
Rockville, Maryland 20852

Re: K071896
Trade/Device Name: Fox 940 Diode Laser
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: December 07, 2007
Received: December 07, 2007

Dear Ms. Paulson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071896

Device Name: Fox 940 Diode Laser

Indications for Use:

The Fox 940 Diode Laser is indicated for:

Surgical applications requiring the ablation, vaporization, excision, incision, hemostasis, or coagulation of soft tissues in medical specialties including dermatology, gastroenterology, general surgery, genitourinary, gynecology, neurosurgery, otolaryngology, orthopedics, ophthalmology, pulmonology, and thoracic surgery

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhouse

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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